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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,271	02/06/2004	James M. Lipton	54275.8021.US01	8489

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EXAMINER	
TATE, CHRISTOPHER ROBIN	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/774,271	LIPTON, JAMES M.	
	Examiner	Art Unit	
	Christopher R. Tate	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 July 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0704*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-23 are presented for examination on the merits.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions of nucleotide and/or amino acid sequences set forth in 37 CRR 1.821(a)(1) and (a)2. However this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 [including the apparent fail to submit a paper copy as well as a computer readable form (CRF) of the sequence listing, as well as properly identifying each sequence within the disclosure with an appropriate --SEQ ID NO:-- following each recitation thereof]. Please note that Applicants are required to provide an initial or substitute paper copy and CRF of the "Sequence Listing", as well as a statement that the content of the paper and CRF copies are the same and/ where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825 (d).

Claim Objections

Claim 19 is objected to because of the following informalities: In lines 1 and 2, there are apparently two typographical errors - i.e., "malabsorbtion" should be replaced with --malabsorption-- and "omprising" should be replaced with -- comprising--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating complications associated with malabsorption conditions of the gastrointestinal tract including complications related to celiac disease, does not reasonably provide enablement for preventing such complications. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants have reasonably demonstrated/disclosed that the claimed combination of ingredients is useful as a therapeutic composition for treating complications associated with malabsorption conditions of the gastrointestinal tract including complications related to celiac disease and/or reducing the risk thereof. However, the claims also encompass using the claimed combination to prevent such conditions which is clearly beyond the scope of the instantly disclosed/claimed invention. Please note that the term "prevent" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does "treating", especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies (other than certain vaccination regimes) - including preventing complications associated with malabsorption conditions of the gastrointestinal tract including complications related to celiac disease (which clearly are not recognized in the medical art as being totally preventable).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is rendered vague and indefinite by the ambiguous phrase "derivatives of *a*-MSH" - i.e., the metes and bounds of this phrase are not clearly nor adequately delineated. For example, a derivative of *a*-MSH could be anything from a carbon, hydrogen, or oxygen atom, an amino acid, a fragment of an amino acid, or some other inactive fragment of *a*-MSH (such as a short side-chain), to name a few. In addition, it is unclear as to how many derivatives are contemplated by the plural phrase "derivatives of *a*-MSH" - e.g., 2, 20, 1000 derivatives?

Claim 21 is rendered vague and indefinite because it does not appear to further limit the invention defined by claim 19 (from which claim 21 ultimately depends) - i.e., claim 19 already recites that the composition comprises "alpha-MSH in combination with derivatives of alpha-MSH". In addition, if Applicant is attempting to further define the alpha-MSH, *per se*, please note that alpha-MSH is a known compound and, therefore. it is unclear as to how alpha-MSH can comprise a derivative of alpha-MSH since alpha-MSH must necessarily define the full alpha-MSH compound. Accordingly, it is suggested that claim 21 be canceled.

Claim 22 recites the limitation "the derivative of alpha-MSH" in line 1. There is insufficient antecedent basis for this limitation in the claim. Please note that the singular term "derivative" therein lacks antecedent basis because it depends from claims 19 and 21 which both recite the plural term "derivatives". To hasten prosecution, it is suggested that claim 19 be

amended, at line 2, so as to recite --in combination with a derivative of alpha-MSH, wherein the derivative is VPKccKPV (SEQ ID NO:5)-- , and that claim 22 be canceled in response to this Office action (in addition, please note that Applicant must comply with the sequence requirements, as discussed above - including with respect to SEQ ID NO:5).

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rajora et al. (Peptides, 1997 - IDS ref BB), Oktar et al. (Peptides, 2000 - IDS ref AY), and Lipton et al. (Annals NY Acad. Sci., 1998), in view of Ruepp (US 2002/0012708), Kennedy (internet article concerning J. Natural Health, 2002 - IDS ref AR), as well as the admitted state of the art.

A pharmaceutical composition for treating malabsorption conditions comprising alpha-MSH in combination with alpha-MSH derivatives and artichoke leaf extract is claimed, as well as a method of treating/preventing malabsorption conditions of the gastrointestinal tract including colitis and other gastrointestinal inflammatory-type disorders via administering a therapeutically effective amount of alpha-MSH in combination with a therapeutically effective amount of artichoke extract to a subject having been diagnosed with such a disorder.

Rajora et al. beneficially disclose that alpha-MSH markedly improves inflammatory bowel disease characteristics, such as experienced in Crohn's disease and ulcerative colitis, in mouse models (see entire document including Abstract, Introduction, and Discussion).

Oktar et al. similarly beneficially disclose that alpha-MSH provides a broad and potent anti-inflammatory protective role on colonic lesions in rat models having induced colonic inflammation, such as experienced with Crohn's disease and inflammatory bowel disease (see entire document including Abstract, Introduction, Discussion).

Lipton et al. also beneficially disclose that alpha-MSH and derivatives thereof provides effective anti-inflammatory activity versus all major models of inflammation including experimental inflammatory bowel disease (see, e.g., Abstract). In addition, please note that Applicant readily admits that recent studies indicate alpha-MSH participates in the anti-inflammatory response in the duodenal mucosa of celiac patients (see, e.g., paragraph [0014]).

None of the first three cited references expressly teach the further incorporation and/or administration of artichoke leaf extract to such a subject.

Ruepp beneficially teaches that artichoke leaf extract is useful as an active agent in treating inflammatory diseases of the bowel, including Crohn's disease (see, e.g., paragraphs [0150], [0155], and claim 1).

Kennedy also beneficially discloses that artichoke leaf extract provided improvement to patients with irritable bowel syndrome, a well known inflammatory bowel disease (see first page of internet article: IDS ref AR - concerning the teachings of the 1992 Kennedy publication). In addition, please note that Applicant readily admits that artichoke leaf extract has been shown in the art to reduce symptoms of irritable bowel syndrome (see, e.g., paragraph [0015]).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit (i.e., treating an inflammatory bowel disease/disorder such as from among those instantly claimed) - as well as to treat a subject having been diagnosed with such an inflammatory bowel disease/disorder - since each ingredient is well known in the art for the same purpose, based upon the beneficial teachings provided by the cited references as a whole with respect to their demonstrated gastrointestinal anti-inflammatory activity (as discussed above), and for the following reasons.

It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable. The adjustment of particular conventional working conditions (e.g., treating a particular type of inflammatory gastrointestinal disease/disorder, and/or determining

therapeutically effective amounts of such ingredients therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references (as well as from the admitted state of the art), it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references (as well as the admitted state of the art), especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher R. Tate
Primary Examiner
Art Unit 1655